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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,397	09/29/2006	Irene Corthesy-Theulaz	3717519-00723	8632
29157 K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690	7590 10/25/2011		EXAMINER EBRAHIM, NABILA G	
			ART UNIT 1618	PAPER NUMBER
			NOTIFICATION DATE 10/25/2011	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary**Application No.**

10/595,397

Applicant(s)

CORTHESEY-THEULAZ ET AL.

Examiner

NABILA EBRAHIM

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 8 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8 and 10-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The receipt of the amended list of claims and Applicant's arguments dated 08/23/2011 is acknowledged.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of Claims:

Claims 1-3, 8 and 10-14 are pending in the application.

Claims 5 and 9 were canceled.

Claims 12-14 are new.

The following rejection is newly applied and necessitated by new amendments to the claims:

Claim Rejections - 35 USC § 103

Claims 1-3, 8 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. US Publication 20010014322 (Chen) in view of Silfversparre et al. US 7198936 (Silfversparre) and further in view of Farmer et al. US 7374753 (Farmer).

Chen teaches a beneficial microbe composition, protective materials for the microbes, method to prepare the compositions and uses thereof. The invention provides a microbe composition which: (1) exerts a control mechanism for the micro ecological balance between enteric microbes and their human host; (2) is antagonistic to pathogens and/or potential pathogens such as salmonella, shigella, E. coli and vibrio cholerae, especially when the pathogens and/or potential pathogens are resistant to various antibiotics; (3) is effective in treating various kinds and degrees of diarrhea; (4) and is effective in decreasing the levels of endotoxin [0022]. The composition contains proteins such as 3.5-4% skimmed milk protein and 3% yeast extract [0061 and claim 15]. Note that the milk protein includes whey. It is also noted

that reciting "the effects of infection includes failure of gut epithelial integrity diarrhea and other COX-2 mediated effects" in claim 2 are inherent effects of such infections and is inherently included in such patients. The composition is used orally as required in instant claim 11 [see all patent publication e.g. paragraphs 0179 and 180].

Chen is silent towards meat peptones.

Silfversparre teaches a method for growth of bacteria (gram-negative bacteria) minimizing the release of endotoxins from the bacteria into the surrounding medium and without acetic acid formation (abstract and claim 1.) An example of gram-negative bacteria E-coli (claims 10 and 11). The reference also teaches that examples of medium components include soy meal, fish meat, yeast extract, soluble whey peptones of casein, soy, fish, and meat (table 1.) The reference also indicates the equivalency of different types of peptones and also the equivalency of soy and meat proteins.

Therefore, it would have been obvious to a person having ordinary skill in the art at the time the current invention was made to use ingredients such as peptones (including meat peptones) disclosed by Silfversparre in the composition taught by Chen to enhance the reduction of endotoxins level caused by gram-negative bacteria such as e-coli.

Neither of the references teaches using the composition for treating endotoxin as an adjuvant.

Farmer teaches a composition for oral administration to the intestinal tract for inhibiting bacterial gastrointestinal infections. The compositions of the invention suitable for use in preventing, treating or controlling gastrointestinal bacterial infections, particularly infant bacterial infections, by organisms capable of producing enterotoxins and infection. The composition can be in the form of a pharmaceutically acceptable carrier suitable for oral administration to a

human infant, preferably, a powdered food supplement, an infant formula or an oral electrolyte maintenance formulation (col. 4, lines 27+).

It would have been obvious to a person having ordinary skill in the art at the time the current invention was made to use the composition made by Chen and modified by Ernest as a pharmaceutical carrier as disclosed by Farmer because Farmer teaches that compositions for treating enterotoxic infections can be used as pharmaceutically acceptable carrier suitable for oral administration to a human infant, preferably, a powdered food supplement, a infant formula or an oral electrolyte maintenance formulation (col. 4, lines 27+).

Response to Arguments

Applicant's arguments filed 08/23/2011 have been fully considered but they are not persuasive. Applicant arguments are based on the deficiency of the references Chen Brody and farmer in disclosing the use of "meat peptones". To respond to the arguments, Brody was withdrawn from the rejection since the reference teaches whey but not meat peptones. Newly added reference Silfversparre teaches a method for growth gram-negative minimizing the release of endotoxins from the bacteria into the surrounding medium wherein yeast extract, soluble whey peptones of casein, soy, fish, and meat are used in the medium to meet this limitation.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NABILA EBRAHIM whose telephone number is (571)272-8151. The examiner can normally be reached on Monday-Friday 10:00 AM -2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NABILA G EBRAHIM/
Examiner, Art Unit 1618

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618